

**CLAIMS**

1. A lead for modifying the activity of at least a portion of a tissue, the lead comprising:-

electrode means adapted for sensing activity of said at least portion of a tissue and providing a signal characteristic of said activity, said electrode means also adapted for selectively delivering a suitable non-excitatory electric field to said at least portion of tissue to achieve a desired change;

connection means operatively connected to said electrode means for enabling said electrode means to be operatively connected to a suitable control means.

2. A lead according to claim 1, wherein said electrode means comprises at least one unitary electrode, each said unitary electrode being adapted for sensing the activity of said at least a portion of tissue and providing to said control means a signal characteristic of said activity non-simultaneously with respect to the selective generation of said suitable non-excitatory electric field to said at least a portion of a tissue by same said at least one unitary electrode.
3. A lead according to claim 1, wherein said electrode means comprises at least one sensing electrode adapted for sensing said activity of said at least a portion of a tissue and for providing a signal characteristic of said activity, and wherein said electrode means further comprises at least one signal delivery electrode adapted for selectively delivering a suitable non-excitatory electric field to said at least portion of a tissue to achieve a desired change therein.

4. A lead according to claim 3, wherein said lead comprises a plurality of pairs of said electrodes, each said pair comprising a said signal delivery electrode and a said signal electrode in adjacent axial arrangement.
5. A lead according to claim 4, wherein said lead comprises two said pairs of electrodes, the sensing electrode of one said pair of electrodes being in adjacent axial arrangement with respect to the sensing electrode of the other said pair of electrodes.
6. A lead according to claim 5, wherein each said sensing electrode is spaced from the nearest disposed signal delivery electrodes by a distance such as to minimise interference between the said signal provided by the sensing electrode and the field provided said nearest signal delivery electrodes, and such that each said nearest signal delivery electrode provides an electric field that corresponds with said signal provided by the corresponding said sensing electrode.
7. A lead according to claim 6, wherein said distance is between about 2mm and about 10mm, and preferably about 5mm.
8. A lead according to claim 5, wherein each said sensing electrode comprises a substantially cylindrical member having a lumen of diameter slightly larger than the outer diameter of said distal portion of said lead.
9. A lead according to claim 8, wherein said cylindrical member comprises a longitudinal length less than the external diameter thereof.
10. A lead according to claim 9, wherein said external diameter is less than 1.2mm.

11. A lead according to claim 3, wherein each said sensing electrode is adapted for sensing tissue impedance, pressure, tension or electrical signal.
12. A lead according to claim 5, wherein each sensing electrode is made from a material chosen from:- Titanium plus Iridium oxide coating; titanium plus titanium nitride coating; platinum iridium plus iridium oxide coating; platinum iridium plus titanium nitride coating; platinum iridium plus sintered platinum coating; titanium; platinum iridium; pyrolitic carbon; or any other conductive material having suitable biostable and biocompatible characteristics.
13. A lead according to claim 5, wherein each said signal delivery electrode comprises one or more electrical conducting elements wound in parallel to a spiral coil-like form having a lumen of diameter slightly larger than the outer diameter of said distal portion of said lead.
14. A lead according to claim 13, wherein said external diameter is less than 1.2mm.
15. A lead according to claim 13, wherein said spiral coil-like form comprises a longitudinal length substantially greater than the external diameter thereof.
16. A lead according to claim 14, wherein said longitudinal length is from about 5mm and about 40mm, and preferably about 20mm.
17. A lead as claimed in claim 13, wherein said spiral coil-like form comprises an effective external surface area of between about 30 square mm and about 250 square mm.

18. A lead according to claim 5, wherein each said signal delivery electrode has an impedance in the range of between about 50 Ohm and about 500 Ohm.
19. A lead according to claim 5, wherein each signal delivery electrode is made from a material chosen from : Titanium plus Iridium oxide coating; (b) Titanium plus titanium nitride coating; Platinum Iridium plus Iridium oxide coating; Platinum Iridium plus titanium nitride coating; Platinum Iridium plus sintered platinum coating; Pyrolytic carbon; or any other conductive material having suitable biostable and biocompatible characteristics and having suitable capacitance.
20. A lead as claimed in claim 5, wherein said electrodes are spaced along the lead such as to occupy a lead length of between about 20mm and about 150mm.
21. A lead according to claim 5, wherein said each electrode of said two pairs of electrodes comprises at least one suitable conductor having suitable distal connector means and proximal connector means for operatively connecting each corresponding said electrode to said connection means, respectively.
22. A lead according to claim 21, wherein said electrodes are carried on a terminal support tube comprised on a distal portion of said lead, said terminal support tube comprising a substantially tubular flexible body member comprising a plurality of longitudinal channels, each said channel adapted to accommodate said at least one conductor corresponding to one of said electrodes, said channels terminating at a corresponding distal terminal area adapted for accommodating a corresponding said distal connector means.

23. A lead according to claim 22, wherein said distal connector means for each said electrode comprises a substantially flat terminal member having an exposed surface substantially larger in area than a transverse cross-sectional area of a corresponding one said at least one conductor, said distal connector means adapted for electrically joining thereto a distal end of a corresponding one said at least one conductor, and said exposed surface adapted for electrically joining thereto a corresponding one of said electrodes.
24. A lead according to claim 22, wherein each one of said electrodes is electrically joined to a said exposed surface of a corresponding one of said distal connector means by means of a laser weld.
25. A lead according to claim 22, wherein each one of said distal connector means is electrically connected to a corresponding one of said at least one conductor by means of crimping said corresponding distal connector means over a distal end of said corresponding at least one conductor inserted into a suitable well provided in said corresponding distal connector means.
26. A lead according to claim 22, wherein said flat terminal member is made from Titanium.
27. A lead according to claim 22, wherein said lead comprises a proximal portion joined to said distal portion thereof, wherein said proximal portion comprises a flexible tubular member having a lumen, a proximal portion of said conductors being carried in said lumen in coiled spiral configuration.
28. A lead according to claim 1, wherein said connection means comprises at least one implantable connector such as IS1 connectors.

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29. A lead according to claim 1, further comprising an ogival intrusion head proximally joined to said distal portion of said lead via a length of suitable tubing.
30. A lead according to claim 29, wherein said tubing comprises a bend.
31. A lead according to claim 30, wherein said bend comprise an angle of between  $30^{\circ}$  and about  $90^{\circ}$ , and preferably about  $45^{\circ}$  when unstressed.
32. A lead as claimed in claim 1, further comprising means for introducing and implanting at least said distal portion of said lead within said at least portion of tissue.
33. A lead according to claim 1, comprising an external diameter such as to enable said lead to be inserted into a suitable blood vessel having a lumen of diameter less than about 1.5mm.
34. A lead according to claim 1, wherein said control means comprise means for receiving said signals from said sensing electrodes and means for determining on the basis thereof the parameters of the electrical field provided by each said signal delivery electrode and the sequencing thereof.
35. A lead according to claim 34, wherein said parameters include at least one of:- the magnitude, shape duty cycle, phase, frequency and duration of said non-excitatory electric field.
36. A lead according to claim 34, wherein said control means comprises means for applying to said signal delivery electrodes a voltage and/or current required for performing an operation chosen from among providing non-excitatory stimuli to the heart or performing pacing or performing defibrillation.

37. A lead according to claim 34, wherein said control means comprises means for generating a non-excitatory electric field having suitable parameters such as to provide the desired change in the activity of the tissue or part thereof.
38. A lead as claimed in claim 1, wherein each said electrode is used for identifying the location thereof relative to the anatomical boundary between the atrium and the ventricle of the heart.
39. A lead as claimed in claim 1, wherein each said electrode is used for identifying the location thereof relative to the anatomical boundary between different heart chambers.
40. A lead as claimed in claim 1, wherein said control means is characterised in being adapted for (I) selectively enabling a suitable non-excitatory electric field to be generated by said electrode means such as to provide the desired modification in the activity of said portion of tissue; and (II) for selectively not generating an electric field; according to at least one at least one characterising feature of said signal previously provided by said electrode means.
- ✓ 41. A lead for modifying the activity of at least a portion of a tissue, the lead comprising:-
- at least one electrode adapted for sensing activity of said at least portion of a tissue and providing a signal characteristic of said activity, said at least one electrode also adapted for selectively delivering a suitable non-excitatory electric field to said at least portion of tissue to achieve a desired change;

connection means operatively connected to said at least one electrode for enabling said at least one electrode to be operatively connected to a suitable control means.

42. A lead as claimed in claim 41, wherein said control means is characterised in being adapted for (I) selectively enabling a suitable non-excitatory electric field to be generated by said at least one unitary electrode such as to provide the desired modification in the activity of said portion of tissue; and (II) for selectively not generating an electric field; according to at least one at least one characterising feature of said signal previously provided by same or other said at least one unitary electrode.

43. A lead for modifying the activity of at least a portion of a tissue, the lead comprising:-

at least one sensing electrode adapted for sensing the activity of said at least portion of a tissue and providing a signal characteristic of said activity; and

at least one signal delivery electrode adapted for selectively delivering a suitable non-excitatory electric field to said at least portion of tissue to achieve a desired change;

connection means operatively connected to said at least one sensing electrode and to said at least one signal delivery electrode for enabling said at least one sensing electrode and to said at least one signal delivery electrode, respectively, to be operatively connected to a suitable control means.

44. A lead as claimed in claim 43, wherein said control means is characterised in being adapted for (I) selectively enabling a suitable



non-excitatory electric field to be generated by said at least one sensing electrode such as to provide the desired modification in the activity of said portion of tissue; and (II) for selectively not generating an electric field; according to at least one at least one characterising feature of said signal previously provided by said at least one signal delivery electrode.

45. A lead according to any preceding claim wherein said tissue is a human heart or part thereof.

46. A lead according to claim 45, optionally for performing pacing of said heart.

47. A lead according to claim 45, optionally for performing defibrillation of said heart.

48. A lead according to ~~any one of claims 1 to 44 and 46 to 47~~, wherein said lead is implanted into a vessel or body cavity using any suitable implantation method.

49. A lead according to ~~any one of claims 1 to 44 and 46 to 47~~, wherein said lead is implanted onto a tissue or organ using any suitable implantation method.

50. A method for applying non-excitatory stimuli to the heart and optionally performing pacing and defibrillation thereof, comprising providing a lead as claimed in ~~any one of claims 1 to 44 and 46 to 47~~, and positioning said distal portion of the lead within a blood vessel of said heart or portion thereof.

51. A method for applying non-excitatory stimuli to said tissue, comprising providing a lead as claimed in ~~any one of claims 1 to 44 and 46 to 47~~, and

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positioning said distal portion of the lead within a blood vessel of said tissue or portion thereof.

52. A method according to claim 51, wherein said tissue is a body organ.
53. A method according to claim 51, wherein said tissue is a body cavity.
54. A method according to claim 53, wherein said body cavity is the heart.
55. A method according to claim 53, wherein said body cavity is a blood vessel.
56. A method according to claim 53, wherein said body cavity is selected from among the urinary bladder, the gastro-intestinal system, the uterus and the larynx.
57. A method for applying non-excitatory stimuli to the heart and optionally performing pacing and defibrillation thereof, comprising providing a lead as claimed in ~~any one of~~ <sup>41 & 42</sup> claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead on the epicardium of said heart.
58. A method for applying non-excitatory stimuli to said tissue, comprising providing a lead as claimed in ~~any one of~~ <sup>41 & 42</sup> claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead on the epicardial surface of said tissue.
59. A method according to claim 58, wherein said tissue is the cervix.
60. A method according to claim 58, wherein said tissue is the uterus.
61. A method according to claim 58, wherein said tissue is the urinary bladder.